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Notice of Allowability

Application No.

09/462,740

Examiner

Peter Paras, Jr.

Applicant(s)

MURAKAMI ET AL.

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the amendment filed on 10/22/03.
2. ☒ The allowed claim(s) is/are 1-3 and 6-7 (renumbered as 1-5).
3. ☒ The drawings filed on 01 February 2001 are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
- * Certified copies not received: _____.
5. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
 - (a) ☐ The translation of the foreign language provisional application has been received.
6. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE**

7. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
8. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No. _____.
 - (b) ☐ including changes required by the proposed drawing correction filed _____, which has been approved by the Examiner.
 - (c) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the margin according to 37 CFR 1.121(d).

9. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|---|
| 1 <input type="checkbox"/> Notice of References Cited (PTO-892) | 5 <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2 <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6 <input type="checkbox"/> Interview Summary (PTO-413), Paper No. _____. |
| 3 <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No. _____ | 7 <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4 <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | 8 <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9 <input type="checkbox"/> Other _____ |

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/22/03 has been entered.

Applicant's amendment received on 10/22/03 has been entered. Claim 1 has been amended. Claim 8 has been cancelled. Claims 1-3 and 6-7 are pending and are under current consideration.

Sequence Compliance

The instant application is now in sequence compliance.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Gordon Kit on 1/9/04.

The specification has been amended as follows:

The title of the invention has been changed to the following: "Transgenic non-human mammals expressing the human complement inhibitor (DAF/CD55)."

On page 26, in line 1 the term "CLAIMS" has been deleted and has been replaced with the phrase "We claim:".

The claims have been amended as follows:

1. A transgenic non-human mammal [comprising a gene of] whose genome comprises a nucleotide sequence encoding a human complement inhibitor (DAF/CD55) [and a promoter, of] operably linked to the porcine complement inhibitor (PMCP), [defined by] consisting essentially of bases 4498 to 5397 of Sequence ID No. 1 [at an upstream locus], said promoter promoting expression of the human complement inhibitor (DAF/CD55), and said mammal expressing the human complement inhibitor in an organ or tissue in amount to prevent hyperacute rejection upon xenotransplantation of said organ or tissue from said transgenic non-human mammal.
2. The transgenic non-human mammal as claimed in claim 1, expressing the human complement inhibitor (DAF/CD55) in endothelial cells.
3. The transgenic non-human mammal as claimed in claim 1, expressing the human complement inhibitor (DAF/CD55) in endothelial cells of organ and tissues of the whole body.

6. The transgenic non-human mammal, as claimed in claim 1, [in which the] wherein said mammal is a domestic or laboratory mammal [animal].

7. The transgenic non-human mammal as claimed in claim 6, [in which the] wherein said mammal is a [transgenic] pig or a [transgenic] mouse.

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The following is an examiner's statement of reasons for allowance: The claimed invention is allowable over the prior art of record because the prior art of record has not fairly taught or suggested transgenic non-human mammals whose genomes express human DAF/CD55 under control of the PMCP promoter, wherein the promoter consists essentially of bases 4498-5397 of SEQ ID NO: 1. Further, the declaration under 37 CFR 1.131 submitted on 10/22/03 has provided data, sufficient to overcome the enablement rejection of record, suggesting that organs or tissue from the transgenic pig embraced by the claims do not experience hyperacute rejection upon xenotransplantation. The amendments to the claims set forth in the Examiner's amendment are for clarity.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

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Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Peter Paras, Jr., whose telephone number is 703-308-8340. The examiner can normally be reached Monday-Friday from 8:30 to 4:30 (Eastern time). The examiner is scheduled to move a new office, on 1/13/2004, having a new telephone number as follows: 571-272-0732.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at 703-305-4051. Papers related to this application may be submitted by facsimile transmission. Papers should be faxed via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Official Fax Center number is (703) 872-9306.

Inquiries of a general nature or relating to the status of the application should be directed to Dianiece Jacobs whose telephone number is (703) 305-3388.

Peter Paras, Jr.

**PETER PARAS
PATENT EXAMINER**

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A handwritten signature in cursive script that reads "Pete Paras".